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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/849,036

05/20/2004

Raimund Schaller

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EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

09/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No. 10/849,036	Applicant(s) SCHALLER, RAIMUND	
	Examiner SARAH AL-AWADI	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12, 13, 16, 17 and 21-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-11, 14-15, 18-20, and 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/27/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed on 08/29/2008.

The Examiner acknowledges the following:

Claims 1-5, 7, 9-11, 17-18, and 26 have been amended with support in the specification to include microcapsules . No new matter has been added.

Claims 1-5, 9-11, 14, 15, 18-20 and 53-55 are currently under consideration.

Claims 6-8, 12-13, 16-17, 21-52, and 56-59 are withdrawn.

INFORMATION DISCLOSURE STATEMENT

The new IDS submitted 5/27/2008 is acknowledged.

WITHDRAWN REJECTIONS

Rejections under 35 USC 103(a)

In light of Applicant's amendments, the rejection to claims 1-5, 9-11, 18-20, 53, and 54 over SCHALLER United States Patent, 6, 254, 947 and TERRY, United States Patent Application 2005/0064176 is hereby **withdrawn**.

In light of Applicant's amendments, the rejection to claims 1, 14, 15, and 55 under 35 over SCHALLER United States Patent 6, 254, 947, in view of TERRY United States Patent Application 20050064176 and further in view of HAMANN United States Patent Application 2004/0091504 is hereby **withdrawn**.

MAINTAINED REJECTIONS

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9-11, 18 and 53 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 16-18 and 30 of U.S. Application No. 2008/0040834 (see PTO-1449). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to a prophylactic article or medical glove comprising an elastomeric base layer, an anti-friction layer and particles that contain an active or dye. The '834 application is directed to a prophylactic article or medical glove, of at least one elastomeric base layer and in some areas an anti-friction layer whereby microcapsules are contained in the anti-friction layer. The claims differ in the size of the particles, with the '834 application claiming 90% of the particles are below 10 microns and the instant claiming the particles have an upper diameter of 500 microns and a lower limit of 10 microns, however, the size of particles is a variable parameter within the art and it is within the skill of a person in the art to increase or decrease the particle size. Furthermore, the '834 application has up to 10% of the particles within the size range of the instant application. Therefore, it would have been obvious to a person of ordinary skill in the art to vary the particle size within the prophylactic article to achieve the particle size of the instant application. Absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

RESPONSE TO REMARKS

Applicant's submit that the ranges of the capsules in the instant and copending application do not overlap with respect to the diameter of the microcapsules.

In response, the Examiner respectfully submits that the size of particles is a variable parameter within the art and it is within the skill of a person in the art to increase or decrease the particle size. For Example ORILANGES et al. United States Patent 5,138,719 teaches microcapsules ranging from 10 to 100 microns. (column 2, line 26) ORILANGES references BUSNEL et al. United States Patent 4,930,522 which teaches microcapsules in a glove within a range of 5 to 50 microns. (column 4, line 14) Furthermore, the '834 copending application has up to 10% of the particles within the size range of the instant application. Therefore, absent evidence to the contrary, it would have been obvious to a person of ordinary skill in the art to vary the particle size within the prophylactic article to achieve the particle size of the instant application.

NEW REJECTIONS

In light of Applicant's amendments which include microcapsule, the following rejections have been newly added:

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9-11, 18-20, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHALLER United States Patent 6, 254, 947 in view of TERRY United States Patent Application, 2005/0064176 and ORILANGES et al. United States Patent 5,138,719.

SCHALLER teaches recesses and raised areas in the anti-friction layer of a multi-layer medical glove article. See Fig. 1. An elastomeric base layer (i.e. carrier layer) with an internal and external surface and an anti-friction layer (i.e. slip layer) comprised of a polymeric material with raised areas and recesses that extend through the anti-friction layer to the base layer. See e.g. col. 9 lines 26-34, column 11 lines 4-7 and lines 25-33; instant claims 1 and 53. The base layer contains synthetic latex (see e.g. col. 5 lines 10-13) or natural latex (see e.g. col. 5 line 9); instant claim 54. With regard to recesses, SCHALLER teaches that between 50 to 90% of the partial area's repeating surface shape deviations are recessed. (column 3, lines 49-51) Fig. 1

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shows the majority of recesses extend to the base layer, and SCHALLER suggests an embodiment within the claimed range. Furthermore, it would have been within the purview of the skilled artisan to optimize the percent ranges of these recesses because SHCALLER teaches that the wealth of micro-cavities (recesses) can considerably reduce the friction potential or contact are between the article and human skin. (column 3, lines 45-48) The thickness of the anti-friction layer is between 2 and 80 microns (see col. 9 lines 31-34; instant claims 19 and 20). SCHALLER does not teach the use of microparticles within the article.

TERRY teaches the use of antimicrobial particles in a coating that is applied to a substrate or device. The substrate is a medical glove or condom made of latex wherein the particles can be applied into one layer (base layer) while keeping a second layer particle free. See e.g. claims 1, 2 and 14. The average particle size is up to about 100 microns making the particle at least 80% of the thickness of the anti-friction layer. See e.g. claim 5; instant claims 2-5. Both water soluble particles (e.g. copper sulfate) and water insoluble particles (e.g. silver zeolite) are taught. See e.g. p[0023]; instant claims 10-11. TERRY contemplates the use of non-silver and non-copper containing particles. See e.g. p[0023] last sentence. Terry does not expressly state that the particles are specifically microcapsules, but it is well known in the art as evidenced by ORILANGES et al. that microcapsules can be placed on the surface of latex or elastomeric materials, with the purpose of reducing frictional forces and releasing an active agent. (column 2, lines 31-44)

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make an article such as a medical glove or condom comprising an anti-friction layer, an elastomeric base layer and pharmaceutically active microcapsules present in or between the layers, as taught by SCHALLER in view of TERRY and ORILANGES. One

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of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single article because of the beneficial effects of incorporating an active pharmaceutical into a glove or condom to prevent the spread of microbes, and to use microcapsules which reduce frictional contact with the skin. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 1, 14, 15 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teaches of SCHALLER (US 6,254,947), TERRY (US 2005/0064176), and ORILANGES et al. (US 5,138,719) as presented above, further in view of HAMANN United States Patent Application 2004/0091504.

The combined teaches of SCHALLER, TERRY AND ORILANGES et al. teach recesses and raised areas in the anti-friction layer of a multi-layer medical glove wherein microcapsules can be present in the glove or condom, as taught above.

The combined references do not teach the use of plant extracts or particular vitamins within the article.

HAMANN teaches a multi-layer prophylactic article or glove wherein a plant extract is incorporated into an elastomer layer of the article or glove. See page 6 paragraph [0038] and claim 37. The extract is incorporated into the inner layer, between the layers, in contact with the skin on the wearer or at all of the mentioned areas. See Figures 3-9. The extract is taught to contain therapeutic components such as anti-microbial or anti-aging. See claim 3. The plant

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extract consists of vitamins such as E, A, C and Nopal. See claims 30, 33, 34 and 35; instant claims 4, 15 and 55.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a medical glove or condom comprising plant extracts or vitamins, as taught by the combined teaches of SCHALLER, TERRY, and ORILANGES further view of HAMANN. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single glove or condom wherein particles of plant extracts and vitamins are incorporated into the article because of the beneficial effect anti-microbials and vitamins have on anti-aging (such as moisturizing) and microbe control, as taught by HAMANN. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this

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final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678.

The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615